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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. FSIS-2014-0040]

RIN [0583-AD57]

Eligibility of Lithuania to Export Meat and Meat Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to add the Republic of Lithuania (Lithuania) to the list of countries eligible to export meat and meat products to the United States. FSIS has reviewed Lithuania's laws, regulations, and inspection system, as implemented, and has determined that they are equivalent to the Federal Meat Inspection Act (FMIA), the regulations implementing this statute, and the United States food safety system for meat and meat products.

Under this final rule, meat from cattle, sheep, swine, and goats slaughtered in Lithuania, or parts or other products thereof, processed in certified Lithuanian establishments, will

be eligible for export to the United States. All such products will be subject to reinspection at United States ports of entry by FSIS inspectors.

DATES: <u>Effective:</u> [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Dr. Daniel L. Engeljohn,
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SUPPLEMENTARY INFORMATION:

Background

On December 17, 2014, FSIS published a proposed rule in the <u>Federal Register</u> (79 FR 75073) to add Lithuania to the list of countries eligible to export meat and meat products to the United States (9 CFR 327(b)). This final rule is consistent with the proposed rule.

As is explained in the proposed rule, under the FMIA and implementing regulations, meat and meat products imported into the United States must be produced under standards for safety, wholesomeness, and labeling that are equivalent to those of the United States (21 U.S.C. 620). The FMIA also requires that the livestock from which such imports are produced be slaughtered and handled in connection with slaughter in a manner that is

consistent with the Humane Methods of Slaughter Act (7 U.S.C. 1901-1906).

Section 327.2 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export meat and meat products to the United States. Paragraph 327.2(a) requires that a foreign country's meat inspection system provide standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's laws and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem inspection, humane methods of slaughter and handling, and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering and preparation of product by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at establishments certified to export; (7) official controls

over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the FMIA and its implementing regulations (9 CFR 327.2(a)(2)(ii)).

The country's inspection system must also impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) national government control and supervision over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification and residue standards; and (7) any other inspection requirements (9 CFR 327.2(a)(2)(i)).

Evaluation of the Lithuanian Meat Inspection System

In 2004, the government of Lithuania initially requested approval to export meat, poultry, and egg products to the United States. In January 2012, Lithuania amended its request to include only meat and meat products. FSIS then began to evaluate Lithuania's inspection system to determine whether it is equivalent to the United States' system.

FSIS conducted a document review of Lithuania's meat inspection system through information provided on FSIS's Self-

Reporting Tool (SRT)¹ to determine whether its system is equivalent to that of the United States. FSIS examined the information submitted by Lithuania to verify that the following equivalence components were addressed satisfactorily with respect to standards, activities, resources, and enforcement:

(1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Point Systems; (5) Chemical Residue Testing Programs; and (6) Microbiological Testing Programs. From that review, FSIS concluded that Lithuania's laws, regulations, control programs, and procedures were sufficient to achieve the level of public health protection required by FSIS.

FSIS then proceeded with an initial on-site audit of Lithuania's meat inspection system in September 2012 and concluded that Lithuania's system met each equivalence component except sanitation. Lithuania's State Food and Veterinary Service (SFVS), which is Lithuania's central competent authority in charge of food inspection, took immediate corrective actions to address the audit team's findings and provided a corrective action plan, which included new regulations, procedures, implementation measures, and verification activities. FSIS

¹ The SRT is a standardized questionnaire that FSIS provides to foreign governments to gather information that characterizes foreign inspection systems according to the six equivalence components and as required by 9 CFR 327.2(a)(2)(iii). FSIS asks foreign governments to submit documentation, such as their inspection system laws, regulations, and policy issuances, that supports their responses to the SRT questions.

reviewed the plan and concluded that it addressed all of the audit findings.

FSIS conducted a second on-site audit in September 2013 to verify that all outstanding issues identified during the previous audit had been resolved and that Lithuania had satisfactorily implemented all of the laws, regulations, and instructions to the field that FSIS found to be equivalent during the document review and previous audit. FSIS concluded, on the basis of this audit, that Lithuania had satisfactorily implemented the corrective action plan that it had submitted in response to the 2012 audit.

Consequently, on December 17, 2014, FSIS published a proposed rule to find that Lithuania's meat inspection system is equivalent to the United States' system and, therefore, to add Lithuania to the list of countries eligible to export meat and meat products to the United States. For more detailed information on FSIS's evaluation of the Lithuanian meat inspection system, see the proposed rule (79 FR 75073), and for the full audit reports, go to:

http://www.fsis.usda.gov/wps/portal/fsis/topics/internationalaffairs/importing-products/eligible-countries-products-foreignestablishments/foreign-audit-reports.

Final Rule

After considering the comments received on the proposed rule, discussed below, FSIS concludes that Lithuania's meat inspection system is equivalent to the United States' inspection system for meat and meat products. Therefore, FSIS is amending its meat inspection regulations to add Lithuania to the list of countries eligible to export meat and meat products to the United States (9 CFR 327.2(b)). Under FSIS's import regulations, the government of Lithuania must certify to FSIS that those establishments that wish to export meat and meat products to the United States are operating under requirements equivalent to those of the United States (9 CFR 327.2(a)).

Although a foreign country may be listed in FSIS's regulations as eligible to export meat and meat products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States, including those of USDA's Animal and Plant Health Inspection Service (APHIS). These requirements include restrictions under 9 CFR part 94 of the APHIS regulations, which regulate the importation of meat and meat products from countries into the United States to control the spread of specific animal diseases.

Also, under this final rule, all meat and meat products exported to the United States from Lithuania will be subject to reinspection by FSIS at United States ports of entry for, but not limited to, transportation damage, product and container

defects, labeling, proper certification, general condition, and accurate count.

FSIS will conduct other types of reinspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis to detect any drug or chemical residues or pathogens that may render the product unsafe or any species or product composition violations that would render the product economically adulterated. Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval of the Food and Drug Administration (FDA)), depending on the violation. The import reinspection activities can be found on the FSIS Web site at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/internationalaffairs/importing-products/port-of-entry-procedures.

In addition, Lithuanian meat and meat products will be eligible for importation into the United States only if they are from animals slaughtered on or after the effective date of this final rule.

Summary of Comments and Responses

FSIS received seven comments in response to the proposed rule. One individual supported the proposed rule. Two individuals, a consumer advocacy organization, and three trade associations representing the pork industry, opposed it. After review and consideration of these comments, FSIS is finalizing the regulation as proposed. The following is a brief summary of the relevant issues raised in the comments and FSIS's responses.

1. Animal Diseases

Comment: One individual opposed importing Lithuanian meat and meat products, stating that animal feeding practices in Lithuania would not effectively prevent bovine spongiform encephalopathy (BSE). Three pork industry groups opposed the rule, stating that several cases of African Swine Fever (ASF) reported over the past year in domestic and feral swine populations in Lithuania and adjacent countries would lead to problems in the United States. A consumer advocacy organization stated that allowing Lithuanian products into the United States could lead to the transmission of certain animal diseases into the United States because Lithuania shares common borders with countries that are not free of ASF, Foot-and-Mouth Disease (FMD), Classical Swine Fever (CSF), or Swine Vesicular Disease (SVD) and has trade practices with these countries that are less restrictive than those of the United States.

Agency Response: To export meat and meat products to the United States, countries need to meet the APHIS requirements for animal disease prevention and control. APHIS uses several methods to ensure that harmful animal diseases do not enter the United States. These include actively monitoring the animal disease status of foreign countries and maintaining lists of countries and regions considered to be free (or not free) of certain diseases. If an animal disease is found to exist in a country (or a region within a country) that exports meat, poultry, or egg products to the United States, APHIS requires specific processing steps to ensure that any product from that country or region will not cause the disease to be transmitted to the United States (see 9 CFR part 94).

In addition to these monitoring and processing provisions,
APHIS requires imported meat, poultry, and egg products to have
accompanying documentation regarding their origin, animal
disease status, degree of processing, and intended use. At the
U.S. border, CBP officials verify that such documentation is
accurate and that the products do not pose an animal disease
transmission risk. These steps take place before FSIS reinspects
imported product for food safety and other regulatory
compliance. All meat and meat products that APHIS restricts from
entering the United States because of animal disease concerns

will be refused entry by U.S. Customs and Border Protection (CBP).

In the case of BSE, APHIS takes into consideration the risk status recognition as determined by the World Organization for Animal Health (OIE), or conducts its own BSE risk determination upon request. OIE designates countries as having a negligible or controlled BSE risk. Countries that do not meet those designations are considered to have an undetermined risk. OIE and APHIS currently designate Lithuania as a country with controlled BSE risk. The review of Lithuania's food safety system for potential BSE contamination also indicated that SFVS employs effective measures to prevent Specified Risk Materials (SRM) (materials from cattle that scientific studies have demonstrated can contain the BSE agent in cattle infected with the disease) from contaminating the food supply. Removal of SRMs decreases the risk of introduction of BSE to a negligible level. Therefore, FSIS has determined that Lithuania's measures to remove SRMs from its food supply adequately address the potential risk that the BSE agent could contaminate products destined for the United States.

APHIS currently considers Lithuania to be free of SVD, rinderpest, and FMD. APHIS, however, has placed Lithuania in a "special category" because of its common land border with countries that have not been identified to be free of these

diseases, and because Lithuania's trade practices are less restrictive than those of the United States. Lithuania's trade practices could, therefore, result in a Lithuanian meat supply that is supplemented with animal products from neighboring countries. Establishments in "special category" countries must certify compliance with specific APHIS regulations, which ensure that animals and animal products received by these establishments, and the products produced by them, are not contaminated through contact with regions where these diseases exist (see 9 CFR 94.11(c)(2) and 94.13(c)(2)).

APHIS recognizes that ASF outbreaks have occurred in wild boar and domestic swine in Lithuania. Lithuania has imposed controls, consistent with European Union legislation, to prevent the spread of this disease. These controls restrict the movement of pigs and pig products, including pork, from areas where the disease has occurred. Were APHIS to add any geographic area of Lithuania to the list of ASF-affected regions, Lithuania would be required to comply with 9 CFR 94.8(b)-(d), which mandates cooking, sealing, cleaning, processing, packing, certification, transportation, and handling requirements.

Under the final rule, Lithuania will be eligible to export meat and meat products to the United States, but will be required to meet APHIS's requirements. Because Lithuania's disease status may change with respect to any animal disease,

FSIS will coordinate with APHIS and consider how any change may affect Lithuania's eligibility to export certain types of products to the United States.

2. Domestic Production

<u>Comment</u>: One individual argued that increasing demand for goat meat in the United States should be met through increased local goat production rather than imports. Another individual opposed the rule because the United States already has thousands of meat products in commerce.

Agency Response: The final rule will list Lithuania as eligible to export meat and meat products derived from cattle, swine, sheep, and goats to the United States (9 CFR 327.2(b)). Although Lithuania will be listed as eligible, it is unlikely to export significant quantities of goat meat or meat products to the United States. Lithuania is a net importer of goat meat and does not have export capacity in this area. In 2014, Lithuania imported about \$3,000 worth of such products, less than one metric ton (MT), and did not export any such products.

Currently, the United States imports about 19,000 MT of goat meat per year, of which 98% comes from Australia. Lithuania must be export-capable and price-competitive to compete in this market. As is discussed in the economic analysis below,

Lithuania has stated that it intends to export only canned,

dried, smoked beef and pork products to the United States at this time.

3. Adequate Regulation

<u>Comment</u>: One individual stated that the FDA was unqualified to certify Lithuanian establishments seeking to export meat or meat products to the United States.

Agency Response: Under 9 CFR 327.2(a)(3), the government of Lithuania must certify to FSIS that those establishments that wish to export meat and meat products to the United States are operating under requirements equivalent to those of the United States. These certifications are subject to review by FSIS. FSIS also conducts periodic equivalence audits of countries eligible to export meat, poultry, or egg products to the United States and will do so for Lithuania. Every imported meat or meat product must enter the United States through an official import inspection establishment and be reinspected by an FSIS import inspector.

4. Audit Report Findings

Comment: A consumer advocacy organization expressed several concerns regarding the two audits of Lithuania's meat inspection system. The organization stated that: (1) the reports are incomplete because they fail to include establishment checklists used by the FSIS auditor to evaluate how well the Lithuanian inspection program enforced food safety laws and regulations at

the plant level; (2) the first audit found that Lithuania's SFVS had inexplicably dropped a requirement that establishments seeking to export to the United States maintain written

Sanitation Standard Operating Procedures; (3) the second audit noted that improvement was still needed in Lithuania's inspectors' verification of establishments' compliance with zero tolerance requirements for fecal material, ingesta, and milk on carcasses and meat parts; (4) in the second audit report, audit staff were concerned about the ability of Lithuanian inspection personnel to recognize potential sanitation issues in ready-to-eat processing facilities; and (5) neither audit report mentioned what precautions the Lithuanian food safety authorities would take as a consequence of the 2013 horse meat scandal in the European Union, in which Lithuanian products were implicated.

Agency Response: FSIS's evaluation of all the data collected before, during, and after the on-site audits supports the conclusion that the Lithuanian meat regulatory system achieves a level of protection equivalent to that of the United States. FSIS evaluated how well Lithuania's inspection program enforced food safety laws and regulations at the plant level, including audit checklists for specific establishments. The Lithuania establishment checklists are posted at the following link:

http://www.fsis.usda.gov/wps/portal/fsis/topics/internationalaffairs/importing-products/eligible-countries-products-foreignestablishments/foreign-audit-reports.

The follow-up audit of Lithuania's meat inspection system confirmed that SFVS adequately and effectively addressed all the findings related to the previous FSIS initial equivalence onsite audit conducted from September 10-26, 2012. The FSIS auditor attested that all corrective actions were implemented in a manner consistent with FSIS's inspection requirements. Additionally, SFVS responded adequately to two areas in need of improvement: verifying that establishments' HACCP systems ensure that all portions of carcasses were free of visible contamination with fecal material, milk, or ingesta, and requiring that establishments control the movement of personnel and materials in establishments producing Ready-to-Eat (RTE) products. SFVS required immediate adjustments to establishments' HACCP systems and sanitation programs, introduced correlation sessions to reinforce supervisors' understanding of food safety tasks related to export to the United States, and implemented on-going training programs for the inspection program personnel. SFVS implemented its corrective action plan and provided supporting documents during and after its exit meeting with FSIS. These corrective actions improved the performance of official verification activities and demonstrated SFVS's

commitment to consistently meeting the requirements for exporting meat and meat products to the United States.

In 2013, a variety of meat products in the European Union were found to contain meat which was not declared on the label, including horse meat and pork. In response, the European Commission and EU Member States, including Lithuania, have pursued efforts to ensure the proper labeling of meat products, including increased communication among food safety agencies regarding food fraud, DNA monitoring, revised registration and identification procedures for horses in the EU, increased penalties for fraudulent activity, and stricter origin labeling. Lithuania, as a Member of the EU, is bound by the EU Regulations under which these actions have been taken.

FSIS also verified that SFVS conducts species verification testing of meat and meat products intended for both domestic production and export, in accordance with the SFVS Director Order No B1-23. This testing will ensure that only eligible species will be exported to the United States. Furthermore, the FSIS auditor verified that Lithuanian establishments are required to ensure that food intended for human consumption is adequately labeled or identified to facilitate its traceability in accordance with Article 18 for Regulation (EC) No 178/2002. The identification and labeling requirements include, at least, the source of food, animal byproduct, or ingredients in a manner

that supports effective investigation and traceability. FSIS is confident that the Lithuanian measures in place, along with its reinspection and verification activities at United States ports of entry, will ensure that fraudulently labeled Lithuanian meat products will not enter United States commerce.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule was designated a "nonsignificant" regulatory action under section 3(f) of E.O. 12866. Accordingly, this rule was not reviewed by OMB under E.O. 12866. Economic Impact Analysis

FSIS is adopting, in its entirety, the proposed regulatory impact analysis from the proposed rule.² Lithuania expressed an intent to export canned, dried, or smoked beef and pork products to the United States. Lithuania, however, will not be precluded

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² 79 FR 75075.

from exporting other meat products in the future if the products meet all applicable APHIS and FSIS requirements for those products. Given the limited market in the United States for Lithuanian meat products and Lithuania's low projected export volume, there is likely to be little, if any, impact on the United States economy.

Lithuania is a small beef producer with limited beef export capacity. Its maximum beef export to the world was achieved in 2011, when it exported \$130 million, or 25,000 MT, worth of beef, mainly to the European Union and Russia. Based on analysis of Lithuania's exports to Russia, FSIS estimates that Lithuania has an excess beef export capacity of \$26 million (\$130 million - \$104 million = \$26 million) in value, or 3,000 MT (25,000 MT - 22,000 MT = 3,000 MT) in volume, that could be exported to the United States.

Accordingly, allowing Lithuanian beef exports to enter the 13,050,000-MT⁴ United States beef market is expected to have minimal effect (3,000 MT represents a 0.023% increase), leaving the total United States beef supply almost unchanged. Because importing beef from Lithuania is not expected to greatly alter

³ This data is from Eurostat, the statistical office of the European Union, and is based on Lithuania's official statistics. It is also available at the Global Trade Atlas database at: http://www.gtis.com/gta/secure/gateway.cfm.

⁴ Source: Foreign Agricultural Service (FAS) Production, Supply and Distribution (PSD) data, available at: https://apps.fas.usda.gov/psdonline/psdQuery.aspx.

the United States beef supply, it will not contribute to any price change in that market.

Lithuanian data from CY2013⁵ shows that this country reached its maximum pork export capacity, meaning it will export little, if any, pork to the United States. Considering that the United States pork supply is 11,212,000 MT (CY2013), ⁶ it is unlikely that imports from Lithuania will result in price changes in the United States pork market.

This cost analysis was based on Lithuania's full export capacity. Currently, however, only six Lithuanian establishments intend to export product to the United States. Four are meat processors only, one is a slaughter facility, and one conducts both meat slaughter and processing. Of the four processing facilities, three process beef and pork, and one processes pork only. The slaughter-only facility and the facility that conducts both slaughter and processing both handle beef and pork. The combined export capacity of these six establishments is much less than Lithuania's total export capacity. With no price change expected in U.S. meat markets, the final rule would not lead to any negative effects on U.S. consumers.

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⁵ This data is from Eurostat, based on Lithuania's official statistics. It is also available at the Global Trade Atlas database at: http://www.gtis.com/gta/secure/gateway.cfm.

⁶ Source: FAS PSD data, available at: https://apps.fas.usda.gov/psdonline/psdQuery.aspx.

Lithuanian companies that export product to the United

States and domestic companies that import products from

Lithuania to the United States will incur standard costs such as export fees and freight and insurance costs. They will be willing to bear these costs because of the anticipated financial benefits associated with marketing their products in the United States

The final rule will increase trade between the United States and Lithuania. The volume of trade stimulated by this rule is likely to be small and is expected to have little or no effect on U.S. meat supplies or meat prices. U.S. consumers, however, are expected to enjoy more choices when purchasing meat and meat products. Lithuanian establishments will export commercially sterile meat products, including canned meat products and ready-to-eat products like salamis and other dried and smoked meats to the United States. The final rule expands choices for U.S. consumers and promotes economic competition.

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this final rule will not have a significant impact on a substantial number of small entities in the United States.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export meat and meat products to the United States are required to provide information to FSIS certifying that their inspection systems provide standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided Lithuania with questionnaires asking for detailed information about the country's inspection practices and procedures to assist that country in organizing its materials. This information collection was approved under OMB number 0583-0153. The proposed rule contains no other paperwork requirements.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other

things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this rule and will announce it online through the FSIS Web page located at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/fede
ral-register/interim-and-final-rules.

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which

provides automatic and customized access to selected food safety news and information. This service is available at:

http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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List of Subjects in 9 CFR Part 327

Imported products.

For the reasons set out in the preamble, FSIS amends 9 CFR part 327 as follows:

- 9 CFR PART 327--IMPORTED PRODUCTS
- 1. The authority citation for part 327 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

- § 327.2 [Amended]
- 2. Amend § 327.2(b) by adding "Lithuania" in alphabetical order to the list of countries.

Done at Washington, DC, on: August 13, 2015.

Alfred V. Almanza,

Acting Administrator.

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